



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/539,241

09/05/2007

Peixuan Guo

570024.402USPC

2305

500

7590

06/23/2010

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

701 FIFTH AVE

SUITE 5400

SEATTLE, WA 98104

EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

06/23/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,241	Applicant(s) GUO ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 38-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 28-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/3/08,9/18/07,8/27/07,7/30/07,7/19/07.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 03/24/2009 is acknowledged. The traversal is on the ground(s) that the required species election to a nucleotide analog is not limited to the heterologous component. The claims are interpreted such the entire pRNA structure can comprise a modified nucleotide.

With respect to the species election of circularly or non-circularly permuted pRNA, this requirement has been withdrawn as a search would reveal art for both structures. With respect to a species election of biologically active RNA, this requirement is withdrawn.

Status of the Application

Claims 1-48 are pending. Claims 1-8, and 28-37 are currently under examination. Claims 38-48 are withdrawn as being drawn to a non-elected invention.

Information Disclosure Statement

The submission of the Information Disclosure Statements on 12/03/2008, 09/18/2007, 8/27/2007, 7/30/2007 and 7/19/2007 is in compliance with 37 CFR 19.7. The information disclosure statements have been considered by the examiner and signed copies have been placed in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 6 is drawn to a non-circularly permuted pRNA. The specification does not appear to provide support for this claim limitation. Throughout the specification when referring to a permuted pRNA, it is in the context of a circularly permuted pRNA. Furthermore the amendment filed 04/02/2008, adding the limitation “-non-circularly permuted pRNA” represents a departure from the claims as originally filed. If Applicant believes that such support is present in the specification and claimed priority documents, Applicant should point, with particularity, to where such support is to be found.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1635

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 28, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (Journal of Biol. Chem 2000 of record cited on IDS filed 07/19/2007).

The instant claims are drawn to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers and wherein each pRNA independently comprises a heterologous component.

Chen et al. teach a pRNA multimer comprising a plurality of pRNA wherein the pRNA comprises heterologous components. The instant specification in paragraph [0057] defines a heterologous component as any sequence that is different than the wild-type sequence. Chen et al. teach changes to the pRNA and incorporates nucleotides that are different than the wild-type structure (see entire reference and Figure 1).

Thus, Chen et al. anticipates the instant claims.

Claims 1-6, 28-32, and 35-37 are rejected under 35 U.S.C. 102(a) as being anticipated by Hoeprich et al. (Gene Therapy 2003 of record cited on IDS filed 07/19/2007).

The instant claims are drawn to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers wherein each pRNA independently comprises a heterologous component, wherein the at least one chimeric pRNA comprises an end-

Art Unit: 1635

labeling agent and wherein at least one pRNA incorporates at least one nucleotide analog.

Hoeprich et al. teach a polyvalent multimeric complex comprising a plurality of pRNA chimers comprising heterologous components of which are small therapeutic RNA molecules such as siRNA and ribozymes all of which comprise antisense RNA (see Figure 1). Hoeprich et al. teach the pRNA can comprise an end-labeled agent.

Thus Hoeprich et al. anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, and 28-37 rejected under 35 U.S.C. 103(a) as being unpatentable over Hoeprich et al. (Gene Therapy 2003 of record cited on IDS filed 07/19/2007) and Bennett et al. (US Patent No. 5,998,148).

The instant claims are drawn to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers wherein each pRNA independently comprises a heterologous component, wherein the at least one chimeric pRNA comprises an end-labeling agent and wherein at least one pRNA incorporates at least one nucleotide analog.

Hoeprich et al. teach a polyvalent multimeric complex comprising a plurality of pRNA chimeres comprising heterologous components of which are small therapeutic RNA molecules such as siRNA and ribozymes all of which comprise antisense RNA (see Figure 1). Hoeprich et al. teach the pRNA can comprise an end-labeled agent.

Hoeprich et al. do not teach the pRNA comprises modified nucleotides.

Bennett et al. teach nucleic acid molecules comprising modified nucleotides such as 2'F modifications (see columns 7 and 8). It was well known in the prior art regarding the benefits of incorporating modified nucleotides into nucleic acid sequences to impart increased nuclease resistance and stability. One of ordinary skill in the art would have wanted to incorporate modified nucleotides into the pRNA to increase the nuclease resistance and stability of the molecule. The skilled artisan would have reasonably been expected to be able to modify the pRNA given Bennett et al. teach the steps of which are routine to one of ordinary skill in the art.

Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

Art Unit: 1635

If attempts to reach the examiner by telephone are unsuccessful please contact Fereydoun Sajjadi at 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1635